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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,353	05/20/2005	Masaharu Seno	2005_0586A	7766

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,353	SENO ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response received June 25, 2007 is acknowledged.

Claims 1-5 are pending in the instant application.

Applicant's election of Group I, claims 1-3, drawn to compositions comprising eosinophil cationic protein (ECP) in the reply filed on June 25, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4 and 5 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 25, 2007 as explained above.

Claims 1-3 are under examination as they read on compositions comprising ECP

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising ECF that promote fibroblast proliferation, actin cytoskeleton formation, and survival of PC12 cells growing in serum-free media, does not reasonably provide enablement for therapeutic compositions for diseases caused by a failure in the survival, proliferation and/or differentiation of a cell, such as heart disease, bone disease or neurodegenerative

disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has claimed compositions comprising ECP and pharmacological components or cell biological components. "Pharmacological" and "cell biological" components are defined on pages 8-11, and include ordinary excipients such as phosphate buffered saline. Applicant has also provided data wherein addition of ECF causes fibroblasts to proliferate (Figure 1), fibroblasts and myocytes to develop more extensive actin cytoskeletons (Figures 5 and 8), and nerve-like PC12 cells to survive cell culture without serum (Figure 11). However, the activity of ECP appears to be cell type specific. For example, Figure 1 demonstrates that ECP induced proliferation in fibroblasts, but other tested cells such as smooth muscle (A10), mammary epithelium (HC-11) and human umbilical vessel endothelium (HUVEC) either did not proliferate or were inhibited in proliferation (HC-11 and HUVEC) as compared to control. The growth of many other cell types is known to be inhibited by ECP, such cell types including carcinomas and leukemias (Maeda et al., see entire document, particularly the abstract).

Further, applicant has recited that the ECP compositions are therapeutic compositions suitable for diseases such as heart, bone and neurodegenerative disease. No in vivo data is disclosed wherein ECP compositions were administered to treat any disease, either in humans or in animal models. The specification appears to base the assertion of therapeutic utility upon the observed effects of administering ECP to cultured cells in vitro. Neuronal tumors are characterized by excessive growth and often a failure of differentiation, with the growth of these cells leading to brain damage and potentially death (Elek et al. and Edsjo et al., see entire documents). As such, a composition that promotes the survival of neurons, which is what the instant specification asserts for ECP compositions, would be contraindicated in such patients. Indeed, applicant's data indicating that ECP promotes survival of a nerve like cell line in serum free condition is surprising given that ECP is well known in the art as a neurotoxin (Rosenberg, see entire document particularly the abstract). The

specification does not appear to address this apparent discrepancy concerning the activity of ECP in neuronal tissues. The cytotoxic effects of ECP are known to extend to cell types other than neurons, and ECP mediated destruction of heart muscle has long been reported in the literature (Patella et al. and Rosenberg, see entire documents). Therefore, while ECP may promote actin skeleton rearrangement in myocytes in vitro, it appears that in vivo the localized effects of ECP in the heart are destructive rather than therapeutic.

Thus, in view of the quantity of experimentation necessary, the lack of sufficient guidance in the specification, the lack of working in vivo examples, the unpredictability of the art, and the breadth of the claims, a skilled artisan would be required to perform undue trials and errors to make and use the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/85766 (of record).

The '766 patent discloses ECF in various compositions for the treatment of disease (see entire document, particularly the abstract and page 2. These compositions are disclosed as comprising "cell biological components" such as phosphate-buffered saline and are disclosed for administration by a wide variety of routes (see particularly pages 20-21). ECP is also disclosed as part of cell culture media that is used in assays designed to detect changes in the biological activity of fibroblasts (see particularly pages 26-28).

It is noted that the '766 patent does not appear to disclose the administration of compositions comprising ECP to treat heart, bone, or neurodegenerative disease.

However, the structure of the claimed invention is a product consisting of ECP and a pharmacological component. This structure is present in the pharmaceutical compositions disclosed in the '766 patent. As such, the recitation of diseases is an intended use limitation that does not distinguish the structure of the claimed composition from the structure disclosed in the prior art.

Therefore, the prior art anticipates the claimed invention.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
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Technology Center 1600
September 4, 2007